REMARKS

Reconsideration and withdrawal of the rejections and objections of the application are respectfully requested in view of the amendments to the claims and the specification, as well as the remarks presented herewith, which are believed to place the application into condition for allowance.

Status of the Claims and Formal Matters

Claims 1, 16-19, and 21-30 are currently pending in this application. By this paper, Claim 1 has been amended, without prejudice. Applicants hereby assert the right to file divisional applications to reclaim cancelled subject matter. No new matter has been added by these amendments. Support for the amended recitations can be found throughout the specification.

The Office Action of April 1, 2005 indicated that the specification of a utility application should include the section headings as provided in 37 C.F.R. §1.77(b). The amendments to the specification provided herewith have now added the applicable section headings to the instant application.

Further, the trademark "Duro-Tak 87-2052" was noted in the present application and should be capitalized wherever it appears and be accompanied by generic terminology. The amendments to the specification have now added the generic terminology for "Duro-Tak 87-2052" and "Duro-Tak 87-4098".

The amendments presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§101, 102, 103, or 112. Rather, these amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

Rejections under 35 U.S.C. §112, 1st Paragraph

Claims 1, 16-19, and 21-30 were rejected under 35 U.S.C. §112, 1st paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Office Action contends that the claims recite the skin contact adhesive layer consisting of clonidine and a copolymer consisting of 2-ethylhexyl acrylate and vinyl acetate, while the Example on page 13 uses Duro-Tak-87-4098. It was allegedly unknown if the trademark used by Applicants consists of a copolymer of 2-ethylhexyl acrylate and vinyl acetate only, or if other ingredients exist.

Submitted herewith is documentation comprising the information packaging insert of Duro-Tak 87-2052 and 87-4098, which states that Duro-Tak 87-2052 consists of 2-ethylhexyacrylate, vinyl acetate, butylacrylate, and acrylic acid. Duro-Tak 87-4098 consists of 2-ethylhexylacrylate and vinyl acetate.

The Office Action of April 1, 2005 alleges that Comparative Example 2 and the Example according to the present invention are identical, i.e., both have the same composition and the comparative example carried out without an absorption promoter. It is respectfully submitted that in Comparative Example 2, Duro-Tak 87-2052 was used, however the Example uses Duro-Tak 87-4098. Thus, the Example, but not Comparative Example 2 is in accordance with claim 1, stating that the "copolymer consists of 2-ethylhexyl acrylate and vinyl acetate".

Furthermore, it can be seen from Table 2 on page 14 that the clonidine permeation of the Example within the first 24 hours is superior compared to both Comparative Examples 1 and 2. This corresponds to the object of the present invention as defined on page 4, lines 21 to 22, which mention a release of clonidine "per day".

The Office Action also stated that claims 16, 17, and 30 recite ranges for clonidine, while the Example shows an amount in milligrams. Thus, it is allegedly unclear if the amount used in the Examples falls within the claimed ranges. The amendments to the specification, which now express the amounts of clonidine as a weight percentage, and now conforms to Claims 16, 17, and 30.

Consequently, reconsideration and withdrawal of the rejections under §112, 1st paragraph are respectfully requested.

Rejections under 35 U.S.C. §112, 2nd paragraph

Claim 18 was rejected under 35 U.S.C. §112, 2nd paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Claim 18 is dependent on claim 1, which has closed language that limits the constituents of the skin contact adhesive layer into clonidine and a copolymer consisting of 2-ethylhexyl acrylate and vinyl acetate, however Claim 18 allegedly broadens the scope of claim 1 by further adding other elements to the skin contact adhesive layer. The amendment to Claim 1, made herewith, obviates this rejection.

Thus, in view of the foregoing, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, 2nd paragraph are warranted and respectfully requested.

CONCLUSION

In view of the foregoing, favorable consideration of the claims is earnestly solicited. If however, there is still an outstanding issue; the Examiner is invited to contact the undersigned for its prompt attention.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: _____

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2.0 DESCRIPTION

2.1 Use of Product

Duro-Tak 387-2052 / 87-2052 is a copolymer of 2-ethylhexylacrylate (2-EHA), vinyl acetate (VA), butylacrylate (BA) and glacial acrylic acid (GAA) in an organic solvent solution. This product is typically cast in a thin film and oven dried to remove the solvents. In this dried film form, this product is a pressure sensitive adhesive which is used as a component in transdermal drug delivery systems. Its primary function is to adhere the patches to the skin for the prescribed length of the therapy. The pressure sensitive adhesive may also function as a polymer matrix to hold the drug and any excipients in the formulation. This material is an inactive ingredient in transdermal drug delivery systems.

2.2 Nomenclature

Chemical name:	Acrylate-vinylacetate copolymer solution pressure sensitive adhesive
Proprietary name:	Duro-Tak® 387-2052
Synonyms:	Duro-Tak® 87-2052 (synonym required for the current US computer system) Duro-Tak® 901-1052 (this number was used for this product up until January 1, 1996)

2.3 Appearance

Appearance:	Clear colorless, viscous liquid
Dried-film form:	Clear colorless, pressure sensitive adhesive film

2.4 Duro-Tak 387-2052 / 87-2052 is a random copolymer of 2-ethylhexylacrylate, vinyl acetate, butylacrylate and glacial acrylic acid supplied in an organic solvent solution. In the manufacture of a transdermal drug delivery system, the Duro-Tak 387-2052 / 87-2052 is coated as a thin film and the solvents are removed when the thin film passes through a drying oven.

a. Acrylate-vinylacetate copolymer
consisting of (starting monomers)

2-ethylhexylacrylate	75.9	%
vinyl acetate	4.5	%
butylacrylate	14.7	%
acrylic acid	4.9	%

reaction is initiated by:

2,2'-azobis(2-methyl-propanenitrile)	0.39	%

after the reaction is complete, the crosslinker is added:

aluminiumacetylacetonate	0.44	%

2.4 Composition

Duro-Tak 87-4098 is a random copolymer of 2-ethylhexylacrylate and vinylacetate supplied in an organic solvent solution. In the manufacture of a transdermal drug delivery system, the Duro-Tak 87-4098 is coated as a thin film and the solvents are removed when the thin film passes through a drying oven.

a. Acrylic Copolymer

consisting of (starting monomers):

2 - Ethylhexylacrylate	50	% of total monomers
Vinyl acetate	50	% of total monomers

reaction is initiated by:

2,2' -Azobis (2-methypropanenitrile)	0.3	% on total monomers

residual monomers are scavenged by:

t-Amyl peroxypivalate	0.4	% on total monomers

b. Solvent Blend

The copolymer is supplied at 36.5 – 40.5 % solids in solution with a typical solvent blend consisting of:

Ethylacetate	100	% on total solvents
Stoddard solvent	0.1	% on total solvents

c. Residual Monomers

The polymerization reaction, or conversion of the monomers to polymer, is never 100% efficient due to the different reactivities of the monomers involved. Therefore, residual levels of the starting monomers may be present in the final product. For Duro-Tak 87-4098, the specified limits on residual monomers are as follows:

2-Ethylhexylacrylate	max.	0.1	%
Vinyl acetate	max.	1.5	%